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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/583,334	03/07/2007	Francesco Santangelo	U 016325-6	9753

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EXAMINER	
SPIVACK, PHYLLIS G	
ART UNIT	PAPER NUMBER
1614	
MAIL DATE	DELIVERY MODE
12/03/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/583,334	SANTANGELO, FRANCESCO	
	Examiner	Art Unit	
	Phyllis G. Spivack	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 August 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4 and 10* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4, 10* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Applicant's Amendment filed August 13, 2008 is acknowledged. Claims 5-9 are canceled. New claim 10 is presented. Accordingly, claims 1-4 and 10 are now under consideration.

An amended Abstract is noted.

Those objections and rejections set forth in the first Office Action that are not herein reiterated are withdrawn. The following objection and rejections represent the only objection and rejections applied to the present claims.

The disclosure is objected to for the following informality: In claim 1 the term "hemodialysis" appears twice.

Appropriate correction is required.

Applicant is again requested to send a complete list of his co-pending and related applications drawn to the administration of cystine and/or cysteine.

Claims 1-8 were rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement in the last Office Action because the claims contains subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention. The specification fails to describe the administration of cystine, cysteine or mixtures thereof for use in any treatment or prevention modality.

Applicant states in the corresponding application before the European Patent Office the question of efficacy was raised, and Applicant responded by

submission of a test note. Applicant states a copy of that note is submitted with the present filing.

No such "test note" is of record in the present case.

The assertion that Applicant was not in possession of the **full scope** of the claimed method at the time the invention was made is maintained. Adequate description requires more than a mere statement that preventing or treating oxidative stress resulting from hemodialysis in a patient suffering from chronic kidney failure or End-Stage Renal Disease is part of the invention. The skilled artisan could not "immediately envisage" the claimed methods drawn to a prevention modality based on the description provided in the disclosure.

The rejection of record is maintained over claims 1-4 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement.

Claims 1-8 were rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention in the last Office Action. The claims are directed to the prevention or treatment of oxidative stress resulting from hemodialysis in patients suffering from chronic kidney disease or End-Stage Renal Disease comprising administering cystine, cysteine or mixtures thereof. The specification does not reasonably provide enablement for methods of <u>prevention</u> within the full scope of the claims.

Applicant argues in the present case, prevention is merely "100% treatment" when the treatment is so effective that oxidative stress is avoided.

Such an assertion of "100% treatment" is clearly not supported by the instant specification. On page 3 of the specification, only a broad general statement of "administration of cystine and/or cysteine for the prevention and treatment of oxidative stress resulting from hemodialysis in patient suffering from chronic renal failure" is provided. This mere statement does not provide support for preventing oxidative stress resulting from hemodialysis in patients suffering from chronic kidney disease or End-Stage Renal Disease and is not commensurate in scope with the instant claims. As evidenced by The Merck Manual, chronic renal failure results from numerous causes. Therefore, the outcome of a particular therapeutic regimen is unpredictable.

Because no guidance is provided drawn specifically to methods of prevention, the rejection of record of claims 1-4 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains to practice the method, is maintained.

In the last Office Action claims 1-8 were rejected under 35 U.S.C. 103(a) as being unpatentable over Yamamoto et al., U.S. Patent 4,794,124, in view of Dall'Aglio et al., WO 0053176.

It was asserted Yamamoto teaches the oral administration of cysteine in amounts of 10-5000 mg to treat diabetic nephropathy, i.e., any pathology of the kidney. According to The Merck Manual, the most common cause of end stage renal disease is diabetic nephropathy. However, Dall'Aglio teaches the administration of cysteine as a

detoxicating agent to treat oxidative stresses. Dall'Aglio teaches "oxidative stress" to mean any physiological and/or pathological condition characterized by an increase in the production of peroxides and free radicals in general, such as in the case of diabetes.

Applicant argues the present claims are novel and non-obvious over the prior art, and new claim 10, particularly, is specifically directed to a method in which the relationship of the treatment with cysteine or cystine with dialysis is set out. Even though Applicant agrees "Dall'Aglio teaches cysteine may be used to treat conditions caused by oxidative stress, and diabetes is a possible cause of oxidative stress, Applicant argues the prior art does not teach the specific problems that arise when patients are subjected to hemodialysis. The teachings of Sela et al., Kidney International, is provided as evidence that oxidative stress is associated with hemodialysis.

Applicant's arguments have been given careful consideration but are not found persuasive. The rejection of record of claims 1-4, and presently extended to include new claim 10, under 35 U.S.C. 103 is maintained.

In view of the combined teachings of Yamamoto and Dall'Aglio, one skilled in the nephrology art would have been motivated to administer cysteine to treat the oxidative stress resulting from hemodialysis with a reasonable expectation of success. A clear association between oxidative stress and hemodialysis is taught by Sela. Dell'Aglio teaches the administration of cysteine to treat oxidative stress. According to Yamamoto, diabetic nephropathy is commonly caused by end-stage renal disease, and cysteine in amounts of 10-5000 mg is effective in the treatment of nephropathy.

No claim is allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this Final Action is set to expire THREE MONTHS from the mailing date of this Action. In the event a first reply is filed within TWO MONTHS of the mailing date of this Final Action and the Advisory Action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the Advisory Action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the Advisory Action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this Final Action.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Phyllis G. Spivack whose telephone number is 571-272-0585. The Examiner can normally be reached on 10:30 AM-7 PM.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Ardin Marschel, may be reached on 591-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

November 27, 2008

/Phyllis G. Spivack/
Primary Examiner, Art Unit 1614